Maryland Health Care Commission
Clinical Advisory Group (CAG) on Cardiac Surgery and PCI
Summary of Meeting: January 10, 2013

CAG members present in person:

Loren Hiratzka, Co-Chair
James Gammie, M.D.
George Groman, M.D.
Christopher Haas, M.D.
Deborah Harper, R.N.
Peter Horneffer, M.D.
Keith Horvath, M.D.
Yuri Deychak, M.D.
Paul Massimiano, M.D.
Michael Peskin, M.D.
Jeffrey Quartner, M.D
Mitchell Schwartz, M.D.
Timothy Shanahan, D.O.
Gary Walford, M.D.
Stafford Warren, M.D.

CAG members participating by phone: Lori Hollowell, R.N. and Sharon Sanders, R.N.

MHCC Staff:
Ben Steffen, Executive Director
Christina Daw
Eileen Fleck
Paul Parker
Sondra McLemore

Presiding Co-Chair **Loren Hiratzka, MD,** opened the meeting at 1:00 pm and asked for introductions. Following the introductions, he asked for any corrections or additions to the written summary of the December 13, 2012 meeting. There were none.

Before beginning the substantive part of the meeting agenda, Christina Daw and Paul Parker made preliminary remarks. Ms. Daw noted that the next two meetings of the CAG are scheduled for **February 28 and March 14, 2013** and that a tentative meeting date of **April 11** for an additional meeting, if needed, has been established. Today's meeting will focus on finishing up consideration of recommendations of the CAG for regulatory oversight of cardiac surgery but we will be circling back to PCI in February. Mr. Parker reminded the Advisory Group that we will be beginning the next two meetings one-half hour earlier, beginning at 12:30 pm, so members may want to get to the venue a little earlier for lunch before the earlier meeting time. The February and March meetings will be at the BWI Marriott Hotel, very close to today's meeting at the BWI Hilton. He also announced that Christina Daw would be leaving the MHCC staff in January to start a new job at CMS and that Eileen Fleck, Program Manager in the Center for Hospital Services would be filling Christina's role as lead staff for the CAG. Advisory Group members can communicate with Eileen via e-mail (eileen.fleck@maryland.gov). Her phone number is 410-764-3287.

Dr. Hiratzka outlined his objectives for the meeting and began by briefly reviewing the draft proposal for oversight of cardiac surgery introduced and discussed at the December, 2012 meeting, using slides that included some revisions to the material presented in December and

with some questions for discussion indicated. After this introduction, he opened the floor for discussion.

The following summarizes the primary issues touched on in the discussion that followed and the elements of the Hiratzka proposal for which consensus emerged. It also identifies areas in which further discussion and work is needed.

Structure of a cardiac surgery oversight process

There is consensus that there should be a standing Clinical Advisory Group on Cardiac Surgery and PCI, with a standing Cardiac Surgery Subcommittee (CSS). The CAG and CSS will provide clinical expertise, review data submitted from the cardiac surgery programs, and make recommendations to the MHCC on oversight criteria, quality of care, and the on-going performance review of cardiac surgery programs. The subcommittee structure is as follows.

- Two representatives of each hospital providing cardiac surgery services: one surgeon, one hospital representative.
- Other clinical and administrative members of the CAG to be determined.
- MHCC to provide regulatory perspective, support staff and resources for all CAG activities.
- The respective chairperson of cardiac surgery and the administrator responsible for hospital operations should attest to and be responsible for all reports originating from each hospital. (Having a hospital operations administrator responsible can help ensure that adequate hospital resources are committed to this project.)
- Semi-annual meetings with format and location to be selected by the CAG.

Further discussion is needed between the CAG and MHCC specifying the duties of CSS in focused program review, and the role of the CSS in program review and consideration of program closure.

Assessment of cardiac surgery quality of care.

The CAG was in agreement that the key quality assessment tool will be the Society for Thoracic Surgeons Adult Cardiac Surgery Database (ACSD).

- All hospitals providing cardiac surgery services in Maryland will be required to participate in the STS ACSD (it was noted that all currently participate), and to share STS data (from the hospitals themselves and/or STS) with the MHCC and CAG for review and reporting.
- The CAG agreed that the initial STS report metric would be the composite score for coronary artery bypass graft surgery. Other metrics are to be selected by the CSS.
- There will be semi-annual review of quality metrics, to include the STS ACSD Composite Star Ratings. Of note, the findings on these metrics will be used as a trigger for focused review and greater examination of a given program; they will not determine, by themselves, the closure of a program.

- Because of the time lag in receiving STS reports (normally 6 months until STS releases reports), case volume reports should be submitted to MHCC-CAG at time of data submission to STS.
- The CAG and MHCC will pursue innovative ways to access some or all of the STS data elements in a more timely fashion (e.g., "super user" status for reviewer, as stroke data coordinators have with national stroke registry database). The MHCC and CAG will contact STS about more direct and comprehensive ways of accessing the STS data in a more timely way. Hospitals will be able to perform quality improvement functions with more timely data.

New program application approval

The CAG agreed to continue the current regulatory requirement that a hospital must demonstrate that it can provide at least 200 surgical cases annually without adverse impact on other Maryland state programs, in order to gain approval to establish a new cardiac surgery program. ***Currently, a program is required to reach 200 cases per year after the second year of operation (hence, a two-year "ramp-up" phase).***

Review of data and reports will be performed at the first six and 12-month milestones, with special attention to improving the quality of data submission.

Thresholds for focused program review

Any of the following findings will be triggers for focused program review.

- Annual surgical case volume <100 cases.
    - Focused review of outcomes will include each death.
- Hospitals with consistent excess observed vs. predicted mortality.
- Outlier status for preoperative factors that affect the surgical risk model, or for intraoperative or perioperative outcomes.
    - The CAG noted a strong need for ongoing data auditing, so that the submitted data can be deemed reliable and accurate.
- Note: Michigan is putting in place a threshold of two successive six-month reporting periods with a One Star composite rating; nevertheless, CAG members suggested that other problems would trigger a focused review before this would occur.

Also, any program may request assistance and review from the CAG-CSS at any time.

Thresholds for program closure

The following "triggers" were accepted as reasonable bases for a review in which program closure is considered. However, CAG members noted any recommendation for program closure would be preceded by a thorough review of that program's processes and outcomes.

- Annual case volume threshold: less than 100 cases for two consecutive years.
- Quality – One Star composite ratings for four consecutive six-month reporting periods.

- Other quality thresholds and review findings to be determined by the CSS.

External Peer Review

The CAG agreed that oversight will require systematic blinded review of process, outcome, and other quality measures. These reviews will likely require significant resources that should be provided through the MHCC.

CAG members voiced support for a regular external peer review process that would be distinct and separate from a regulatory oversight review. The former would be conducted in a non-punitive, improvement-oriented environment.

There will need to be further discussion regarding whether the CAG-CSS would be involved with this type of external peer review, or this function would be farmed out. More discussion is also needed regarding whether a model like that in place in New England or Virginia (VCSQI) consortium would be appropriate for this external review, and whether it would be separate from the CAG-CSS.

Data Audit

The CAG agreed that data auditing is necessary, and will examine whether the current random audit process by STS adequately meets that need.

Appropriate Use Criteria

The STS and CathPCI data elements were reviewed by the CAG, and it was concluded that the elements would not address the need for assessing appropriateness of cardiac surgery. Further examination by CAG members on measures of patient selection appropriateness may be required. Several members observed that delivery of PCI services currently has a more visible need for deployment of effective appropriate use determination than cardiac surgery.

Adjournment

Prior to adjourning, Mr. Parker updated the group on the December, 2012 review, by MHCC, of the qualification of the eight non-cardiac surgery hospitals that provide non-primary PCI for an exception from the requirement to obtain a certificate of conformance in order to continue the provision of non-primary PCI. This exception was provided for in the 2012 law that created the CAG. Exceptions to the COC requirements were granted to all eight of these hospitals, based on a finding that the results of the C PORT E research should guide public policy and a finding that the eight programs complied with the existing waiver requirements. Copies of the report considered by MHCC in this review were made available.

Dr. Walford noted that the MHCC website is a valuable resource on all of the issues surrounding PCI and its regulation and commended Ms. Daw for the work she has done in developing the site. Ben Steffen closed with thanks to Ms. Daw for the good work she has done in staffing the CAG up to this point. The meeting was adjourned at approximately 3:30 pm.